

HIPAA PRIVACY REGULATIONS EXTRACT OF PREEMPTION REFERENCES

(67 Fed.Reg. 52182 et seq. (Aug. 14, 2002))

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EXPLANATION

The following document is a tool designed to assist HIPAA-covered persons and entities in analyzing provisions of State law for preemption by the Health Insurance Portability and Accountability Act (HIPAA). The document is an extract of all references to HIPAA preemption of State law set forth in the Final Rule (Standards for Privacy of Individually Identifiable Health Information) issued on August 14, 2002. (67 Fed.Reg. 53182 et seq. (Aug. 14, 2002).)

Please forward any comments, corrections, etc. to the attention of:

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HIPAA Privacy Regulations Extract of Preemption References (67 Fed.Reg. 53182 et seq. (Aug. 14, 2002))

I. Background

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II. Overview of the March 2002 Notice of Proposed Rulemaking (NPRM)

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III. Section-by-Section Description of Final Modifications and Response to Comments

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B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

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3. Parents as Personal Representatives of Unemancipated Minors [fn1: Throughout this section of the preamble, "minor" refers to an unemancipated minor and "parent" refers to a parent, guardian, or other person acting in loco parentis.]

December 2000 Privacy Rule

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March 2002 NPRM

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The Department proposed changes to these standards where they did not operate as intended and did not adequately defer to State or other applicable law with respect to parents and minors. First, in order to assure that State and other applicable laws that address disclosure of health information about a minor to his or her parent govern in all cases, the Department proposed to move the relevant language about the disclosure of health information from the definition of "more stringent" (see § 160.202) to the standards regarding parents and minors (see § 164.502(g)(3)). This change would make it clear that State and other applicable law governs not only when a State explicitly addresses disclosure of protected health information to a parent but also when such law provides discretion to a

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provider. The language itself is also changed in the proposal to adapt it to the new section.

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Overview of Public Comments

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There were also some commenters that were confused by the new proposal and others that requested a Federal standard that would preempt all State laws. . [53200 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

Final Modifications.

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The first change, regarding disclosure of protected health information to a parent, is the same as the change proposed in the NPRM. In order to assure that State and other applicable laws that address disclosure of health information about a minor to his or her parent govern in all cases, the language in the definition of "more stringent" (see § 160.202) that addresses the disclosure of protected health information about a minor to a parent has been moved to the standards regarding parents and minors (see § 164.502(g)(3)). The addition of paragraphs (g)(3)(ii)(A) and (B) of § 164.502, clarify that State and other applicable law governs when such law explicitly requires, permits, or prohibits disclosure of protected health information to a parent.

In connection with moving the language, the language is changed from the December 2000 Privacy Rule in order to adapt it to the new section. Section 164.502(g)(3)(ii)(A) states that a covered entity may disclose protected health information about a minor to a parent if an applicable provision of State or other law permits or requires such disclosure. By adopting this provision, the Department makes clear that nothing in the regulation prohibits disclosure of health information to a parent if, and to the extent that, State or other law permits or requires such disclosure. The Privacy Rule defers to such State or other law and permits covered entities to act in accordance to such law. [53201 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

Response to Other Public Comments

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<u>Comment</u>: Commenters continue to raise preemption issues. A few commenters called for preemption of all State law in this area. Others stated that there should be one standard, not 50 standards, controlling disclosure of protected health information about a minor to a parent and that the NPRM

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approach would burden regional and national health care providers. Others urged preemption of State laws that are less protective of a minor's privacy, consistent with the general preemption provisions.

Response: The Department does not want to interfere with a State's role in determining the appropriate rights of parents and their minor children. The claim that the Privacy Rule introduces 50 standards is inaccurate. These State standards exist today and are not created by the Privacy Rule. Our approach has been, and continues to be, to defer to State and other applicable law in this area.

<u>Comment</u>: One commenter requested the Privacy Rule state that good faith compliance with the Privacy Rule is an affirmative defense to enforcement of contrary laws ultimately determined to be more stringent than the Rule, or that it provide specific guidance on which State laws conflict with or are more stringent than the Privacy Rule.

Response: The Privacy Rule cannot dictate how States enforce their own privacy laws. Furthermore, guidance on whether or not a State law is preempted would not be binding on a State interpreting its own law. [53202 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

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D. Section 164.506—Uses and Disclosures of Treatment, payment, and Health Care Operations

1. Consent

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December 2000 Privacy Rule

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March 2002 NPRM

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Overview of Public Comments

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Final Modifications.

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This Final Rule also includes conforming changes to the definition of "more stringent" in § 160.202...to eliminate references to required consent. . [53211 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

Response to Other Public Comments

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<u>Comment</u>: Some commenters asserted that eliminating the consent requirement would be a departure from current medical ethical standards that protect patient confidentiality and common law and State law remedies for breach of confidentiality that generally require or support patient consent prior to disclosing patient information for any reason. Another commenter was concerned that the removal of the consent requirement from the Privacy Rule will become the de facto industry standard and supplant professional ethical duties to obtain consent for the use of protected health information.

Response: The Privacy Rule provides a floor of privacy protection. State laws that are more stringent remain in force. In order not to interfere with such laws and ethical standards, this Rule permits covered entities to obtain consent. Nor is the Privacy Rule intended to serve as a "best practices" standard. Thus, professional standards that are more protective of privacy retain their vitality. [53212 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

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H. Section 164.520—Notice of Privacy practices for Protected Health Information

December 2000 Privacy Rule

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March 2002 NPRM

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Overview of Public Comments

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Final Modifications.

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Response to Other Public Comments

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Certain other commenters urged that one way to make the notice shorter, as well as to alleviate burden on the covered entity, would be to eliminate the requirement that the notice explain the more stringent State privacy laws. Commenters stated that companies that operate in multiple States will have to develop and print up to 50 different notices, and then update and reissue those notices whenever a material change is made to the State law. These commenters recommended instead that the notice simply state that State law may provide additional protections.

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A few commenters urged that the Department provide a model notice that covered entities could use in their implementation efforts.

Response: The Department does not modify the notice content provisions at § 164.520(b). The Department believes that the elements required by § 164.520(b) are important to fully inform the individual of the a covered entity's privacy practices, as well as his or her rights. However, the Department agrees that such information must be provided in a clear, concise, and easy to understand manner. Therefore, the Department clarifies that covered entities may utilize a "layered notice" to implement the Rule's provisions, so long as the elements required by § 164.520(b) are included in the document that is provided to the individual. For example, a covered entity may satisfy the notice provisions by providing the individual with both a short notice that briefly summarizes the individual's rights, as well as other information; and a longer notice, layered beneath the short notice, that contains all the elements required by the Privacy Rule. Covered entities, however, while encouraged to use a layered notice, are not required to do so. Nothing in the final modifications relieve a covered entity of its duty to provide the entire notice in plain language so the average reader can understand it. See § 164.520(b)(1).

In response to comments regarding a model notice, it would be difficult for the Department to develop a document that would be generally useful to many different types of covered entities. A covered entity's notice must reflect in sufficient detail the particular uses and disclosures that entity may make. Such uses and disclosures likely will be very different for each type of covered entity. Thus, a uniform, model notice could not capture the wide variation in information practices across covered entities. The Department intends, however, to issue further general guidance to help covered entities implement the notice provisions of the Rule. [53242-43 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

§ 160.202 Definitions.

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More stringent means * * *

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

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(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

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5. Amend § 160.203(b) by adding the words "individually identifiable" before the word "health". [53266 Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2000 / Rules and Regulations.]

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5. Amend § 160.203(b) by adding the words "individually identifiable" before the word "health".